REMARKS

The Office Action and the cited and applied reference have been carefully reviewed. No claim is allowed. Claims 1-4 and 8 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

The examiner states that claim 1 is anticipated by the Morgan reference and has no special technical feature, and holds that since the unity of invention is lacking, claim 8 of Group II cannot be rejoined with Group I (claims 1-4).

Applicants believe however that since claim 1 as amended has novelty over the Morgan reference (as discussed below), and Group II now shares a special technical feature with Group I, the two Groups satisfy the requirement for unity of invention. Withdrawal of the restriction requirement and rejoinder of claim 8 with claims 1-4 are respectfully requested.

Claim 1 has been rejected under 35 U.S.C. §102(b) as being anticipated by Morgan because the examiner holds that:

> Morgan teaches that the primary limitation of cancer chemotherapeutic drugs, doxorubicin and anthracyclines, has been dose-dependent cardiac toxicity, which can result in a congestive cardiomyopathy due to myocyte loss (pp. 2343, right column, 2nd paragraph in Discussion). Thus, the patients in the Morgan reference who are under chemotherapy, meet the limitation "in need thereof". Morgan et al. teach the use of G-CSF for hematological support. However, G-CSF was the sole active ingredient administered to

> the patient beginning on day 6, following doxorubicin and cyclophosphamide treatments. The fact that no patient developed severe myofibrillar damage shows the amount is effective. Therefore, Morgan meets each and every limitation of the claims.

This rejection is respectfully traversed.

The present inventors surprisingly discovered that G-CSF has a therapeutic effect on non-ischemic heart failure. In other words, they found that progressive myocardial fibrosis, left ventricular remodeling and heart failure in a patient suffering from non-ischemic heart failure can be ameliorated by administration of G-CSF as the sole active ingredient. Therefore, the feature of the present invention is in treating non-ischemic heart failure by administering G-CSF as the sole active ingredient to a patient suffering from non-ischemic heart failure, as presently recited in amended claim 1.

As defined in the "BACKGROUND ART" section of the specification (page 1, lines 20-22), ischemic heart failure is hypoxia-induced heart failure caused by failure to receive the blood volume required for metabolism. Congestive cardiomyopathy due to myocyte loss that is disclosed in Morgan et al. (page 2343, right column, 2nd paragraph) is a disease in which blood flow stagnates, thereby causing the ambient tissue to fall into hypoxia. This disease is classified under ischemic heart failure, and is not a non-ischemic heart failure as recited in the claims. Accordingly, even though Morgan teaches that a

congestive cardiomyopathy was caused by chemotherapy and that a therapeutic effect of congestive cardiomyopathy was produced by administration of G-CSF, Morgan does not and cannot anticipate the presently claimed invention because congestive cardiomyopathy due to myocyte loss is different from non-ischemic heart failure treated by the present method, and the patient populations are different as well.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1 and 2 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 17 of copending application 10/924,197.

As applicants believe that the §102(b) anticipation rejection of claims 1-4 over Morgan is now obviated, the non-statutory obviousness-type double patenting rejection over later-filed application 10/924,197 is now the only rejection remaining. Accordingly, applicants request that this provisional obviousness-type double patenting rejection be withdrawn to permit the present earlier-filed application to issue without a terminal disclaimer.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By /ACY/
Allen C. Yun
Registration No. 37,971

ACY:pp
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\Y\YUAS\Fujiwara3\Pto\2008-08-13amendment.doc